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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,314

05/17/2005

David Wallach

WALLACH33

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1444

7590

12/15/2006

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/511,314	Applicant(s) WALLACH ET AL.	
	Examiner Sheridan L. Swope	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-34, 42-57 and 66-75 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 20-34, 42-57, and 66-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 20-34, 42-57, and 66-75 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 20-25 and 66-75, drawn to a method of treatment using an NIK polypeptide.

Group II, Claim 26, drawn to a method of treatment using an antibody to an NIK polypeptide.

Group III, Claims 27 and 28, drawn to a method of treatment using a DNA encoding an NIK polypeptide.

Group IV, Claim 29, drawn to a method of treatment using a small molecule modulator of an NIK polypeptide.

Group V, Claims 30, 42-44, 51, 56, and 57, drawn to an NIK polypeptide.

Group VI, Claims 31, 34, 45-48, 54, and 55, drawn to a DNA encoding an NIK polypeptide.

Group VII, Claims 32, 49, and 52, drawn to an antibody to an NIK polypeptide.

Group VIII, Claims 33, 50, and 53, drawn to a small molecule modulator of an NIK polypeptide.

For each of Invention I above, restriction to two of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I-VIII and one of Inventions (A)-(C), one of Inventions (D)-(F) and one of Inventions (G)-(M).

If Invention I is elected, elect one of:

- (A.) IL-2
- (B.) IL-12
- (C.) IL-15

If Invention I is elected, elect one of:

- (D.) SEQ ID NO: 19
- (E.) SEQ ID NO: 18
- (F.) AlyNIK

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If Invention I is elected, also elect one of:

- (G.) Rheumatoid arthritis
- (H.) Osteoarthritis
- (I.) Inflammatory bowel disease
- (J.) Asthma
- (K.) Cardiac infarct
- (L.) Alzheimer's disease
- (M.) atherosclerosis

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I-VIII appears to be that they all relate to NF-kappaB-inducing kinase (NIK). However, NIK was known in the art (O'Neill et al, 1998). Therefore Groups I-VIII share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the products of Groups V-VIII do not share a special common structural and functional feature while, the methods of Groups I-IV do not use the same reagents or produce the same results. In addition, the methods of Groups I-IV do not comprise all of the methods for making or using the products of Groups V-VIII. Accordingly, Groups I-VIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Searching more than one of Groups I-VIII would represent a burden on the Office for the following reasons. Because the products of Groups V-VIII do not share a special structural and functional feature, a search for any one said product would not encompass a search for any other said products. Thus, a search for more than one of the products of Groups V-VIII would be a burden on the Office. A search for any one of the methods of Groups I-IV would not encompass a search for any other said methods because the methods do not share a special technical feature of steps and products used, or results produced. Thus, the search for more than one of Groups I-IV would be a burden on the Office. A search of any one of the products of Groups V-VIII would not encompass a search of any of the methods of Groups I-IV, or vice versa, because said methods are not the only methods of making or using said products. Thus, a search of any one of the products of Groups V-VIII with any of the methods of Groups I-IV would be a burden on the Office.

These inventions lack Unity of Invention for the reasons given above. Furthermore, each invention has acquired a separate status in the art due to their recognized divergent subject matter and, thus, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, *In re Ochiai*, and *In re Brouwer*).

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Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right, if the amendment is presented prior to final rejection or allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Final Comments

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1652



SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER